1645

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HUESCHEN AND SAGE

Kathleen A. Willard

Dated: 26 March 2004

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Applicant	:	Jean-Yves BONNEFOY, Sybille LECOANET, Jean-Peirre AUBRY, Pascale JEANNIN and Thierry BAUSSANT
Serial No.	:	09/831,061
Filed	:	August 31, 2001
Title	:	USE OF AN ENTEROBACTERIUM PROTEIN OmpA FOR SPECIFIC TARGETING TOWARDS ANTIGEN-PRESENTING CELLS
Art Unit	:	1645
Examiner	:	Sarvamangala J. N. DEVI, Ph.D.

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Honorable Commissioner of Patents and Trademarks
Alexandria, VA 22313

RESPONSE AND AMENDMENT UNDER 37 CFR §§ 1.111

Sir:

Responsive to the Office communucation dated February 27, 2004, the Applicants traverse the Office position that the claims, as currently amended, shift away from the elected invention. The Applicants take this opportunity to clarify the Office misconstruction after an unsuccessful telephone interview with the Examiner on March 9, 2004.

The Applicants submit that the Response and Amendment filed December 8, 2003 is fully responsive to the Office Action dated August 29, 2003. Elected Claim 25 was amended to conform to an accepted U.S. method claim for delivering a biologically active substance to antigen-presenting cells and properly recites the active steps of the method. With the amendment, the subject matter of original and elected Claim 26, drawn to the specific binding of OmpA protein to antigen-presenting cells, was incorporated into Claim 25. Likewise, the subject matter of original, and elected Claim 32, drawn to the amino acid sequence of OmpA having SEQ ID No. 2, and original, and elected Claim 34, drawn to covalent coupling of the active substance to OmpA, were incorporated into elected Claim 25. Claims 26, 32 and 34 were consequently canceled as redundant. The Applicants submit that with these amendments, no claims to a new invention were added.

Moreover, the Office position is inconsistant with USPTO procedure. With the Restriction requirement the Office mistakenly defined original Claims 25-39 of elected Restriction Group I, as being drawn to a process of using an enterobacterium OmpA for preparing a composition. Clearly the claims do not set forth any active, positive steps required for a process of using an enterobacterium OmpA for preparing a composition. The mere recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Therefore, the Office interpretation was not only mistaken, but unnecessarily prejudicial. In view of the cited case law, the Applicants respectfully submit that the Office conclusion that the instant invention is drawn to a process of using enterobacterium OmpA for the preparation of a composition is in error.

The claims were originally drafted as European "use" claims, which stated the intended use of the enterobacterium OmpA protein, or a fragment thereof, in a

composition for specific targeting of a biologically active substance into antigen presenting cells. MPEP § 2111.02 provides guidance on the interpretation of "purpose or intended use" in claim language. The MPEP instructs that the context of the entire claim should be considered before concluding that the intended use is a limitation. The MPEP instructs the Examiner to review the entirety of the record to gain an understanding of what the inventors actually invented and intended to encompass by the claim. It would appear that the Office has mistakenly relied on insignificant European "use" language and completely ignored the substance of the claim, namely:

The Claim to

1) using an enterobacterium OmpA protein, or fragment thereof,
2) for specific targeting of a biologically active substance, which is associated with it, to antigen presenting cells
3) wherein....

see Claim 25 of the Preliminary Amendment of May 4, 2001.

The Office's simplistic interpretation of this sophisticated method consists of:

"a method of making a composition using an enterobacterium OmpA protein"

see Office Communication of February 27, 2004, page 1, lines 13-14.

If the Office is going to capriciously limit claim scope, such interpretation must, at least, fulfill the 35 U.S.C. § 101 requirement.

Claims 25-39 as originally filed, which claims are the subject matter of the elected invention of Group I are drawn to European "use" claims which are equivalent to U.S. method claims. Dependent use/method claims provide additional limitations on this method and certainly not limitations on a process for making a composition. The Applicants respectfully request the Office observance of the above noted procedural guidelines and further consideration of the elected method.

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Accordingly, entry of the previously submitted amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,
THE FIRM OF HUESCHEN AND SAGE

By: G. Patrick Sage

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